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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,660	06/12/2001	Eric Dupont	014985.0012	2949
27683	7590	12/24/2003	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/879,660	Applicant(s) DUPONT ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-24 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11, 13 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 14 and 17-20 is/are ~~allowed~~: *free of art*
- 6) ☒ Claim(s) 8, 21 and 24 is/are rejected.
- 7) ☒ Claim(s) 12, 16, 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 8-24 are pending.

Applicants' amendment filed October 3, 2003 is acknowledged. Applicants' response has been fully considered. Claims 1-7 have been cancelled, claims 8, 10, 12, 14, 16 and 17 have been amended, and new claims 20-24 have been added. Claims 9, 11, 13 and 15 are non-elected inventions, thus withdrawn from consideration. Therefore, claims 8, 10, 12, 14, 16, 17 and 20-24 are examined.

Election/Restrictions

2. Applicant has elected Group III, claims 8-19, dipeptide as the unit complexed to a copper metal ion, and antitumor agent in claim 16 in the Response filed February 28, 2003; and the restriction requirement was made final in the previous Office Action dated May 5, 2003. In response to the objection of claims 8 and 16 because of recitation of non-elected invention in the claims, applicants indicate claim 16 has been amended to cancel non-elected subject matter, but argue that claim 8 sets forth compounds included within a Markush group that share a common utility and share a substantial feature disclosed as being essential to that utility, i.e., that of having a carboxyl and an amino group capable of complexing with copper and that targets cells of an angiogenic tissue, thus claim 8 should be examined fully with respect to the elected species and further to the extent necessary to determine patentability (pages 4-5 of the response). This is not found persuasive because the compounds of claim 8 include amino acid (class 436, subclass 90) and dipeptide (class 514, subclass 19), which are classified into different class/subclass and structurally different (e.g., a peptide bond existing in dipeptide but not in amino acid), thus the

Art Unit: 1653

amino acid and the dipeptide do not meet the structural requirement for the unity of invention within a Markush group. Therefore, claims 9, 11, 13 and 15, which are directed to amino acids, along with amino acid part of claim 8 are non-elected invention and withdrawn from consideration.

Objection Withdrawn

Claim Objection

3. The previous rejection of claim 16 is withdrawn in view of applicants' amendment to the claim and applicant's response at page 4 of the amendment filed October 3, 2003.

4. The previous rejection of claims 10 and 14 is withdrawn in view of applicants' amendment to the claim and applicant's response at pages 7-8 of the amendment filed October 3, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 102

5. The previous rejection of claims 8 and 12, under 35 U.S.C. §102(b) as being anticipated by Pallenberg *et al.* (U. S. Patent 6,017,888) or Arena *et al.* (J. Inorg. Biochem. 50, 31-45 (1993)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 5-6 of the amendment filed October 3, 2003.

Claim Rejections - 35 USC § 103

6. The previous rejection of claims 8, 12 and 16-19, under 35 U.S.C. §102(3) as being unpatentable over Arena *et al.* (J. Inorg. Biochem. 50, 31-45 (1993)) taken with Dupont (U. S.

Art Unit: 1653

Patent 6,383,522), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 6-7 of the amendment filed October 3, 2003.

Claim Objections

7. Claims 8, 12, 16 and 22-23 are objected to because the claim contains recitation of non-elected invention.

In response, applicants indicate claim 16 has been amended to cancel non-elected subject matter, but argue that claim 8 sets forth compounds included within a Markush group that share a common utility and share a substantial feature disclosed as being essential to that utility, thus, the objection to claims 8 and 16 should be withdrawn. The argument is not found persuasive because of the reason cited in the section of restriction/election (see paragraph 2).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stack *et al.* (Transactions of the Faraday Society 63 (5), 1136-1145 (1967)).

Stack *et al.* teach the measurement of the heats of formation of chelates of Cu(II) with amino acid or dipeptide Gly-Gly such as Cu(Gly-Gly)₂ (Table 1, pages 1138 and 1141), and the Gly-Gly and copper complex can be a mixture of Cu(Gly-Gly) and Cu(Gly-Gly)₂ (page 1143, paragraph 2). Claims 8 and 24 are anticipated by the reference because the two dipeptide units having both amino and carboxyl groups form the same type of complex with a copper ion as

Art Unit: 1653

indicated in the instant application (See the structure of the complex at page 24), therefore, the $\text{Cu}(\text{Gly-Gly})_2$ complex in the reference would have been expected to have the same physical and chemical properties as the claimed complex.

9. Claims 8, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomicka *et al.* (Zeszyty Naukowe Wydzialu Matematyki, Fizyki, Chemii, [Seria]: Chemia (Uniwersytet Gdanski) 2, 95-100 (1972), see abstract and the search result). The reference cannot be obtained at this time, the reference and the English translation will be forward to applicants, once they are obtained).

Tomicka *et al.* teach the Cu complexes with dipeptides (abstract) such as $\text{Cu}(\text{L-Phe-L-Leu})_2$ (CAS registry number: 54453-29-1) or $\text{Cu}(\text{D-Phe-L-Leu})_2$ (CAS registry number: 54515-62-7; claim 8, 21 and 24). Claims 8, 21 and 24 are anticipated by the reference because the two dipeptide units having both amino and carboxyl groups form the same type of complex with a copper ion as indicated in the instant application (See the structure of the complex at page 24), therefore, the Cu complex with dipeptide in the reference would have been expected to have the same physical and chemical properties as the claimed complex.

Conclusion

Art Unit: 1653

7. Claims 8, 21 and 24 are rejected and claims 8, 12, 16 and 22-23 are objected to. It appears that claims 10, 14 and 17-20 are free of prior art.

Art of Record

The following references also describe the Cu(dipeptide)₂ complexes (see abstract and search result; these references and the English translations will be forward to applicants once obtained):

1. Cu(Ala-Gly)₂, Cu(Phe-Gly)₂ and Cu(Gly-Gly)₂ in Szabo-Planka et al., Journal of the Chemical Society, Dalton Transactions : Inorganic Chemistry 10, 1925-1932 (1989).
2. Cu(Gly-Trp)₂, Cu(Gly-His)₂ and Cu(Gly-Gly)₂ in Poroshin et al., Doklady Akademii Nauk Tadzhikskoi SSR 14 (1), 37-40 (1971).
3. Cu(Gly-Ala)₂, Cu(Gly-DL-norleucine)₂ and Cu(Gly-DL-Leu)₂ in Salakhutdinov et al., Zhurnal Fizicheskoi Khimii 42 (8), 2076-2078 (1968).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1653

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

December 19, 2003

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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